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EXAMINER

GILBERT, SAMUEL G

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte IAN D. FAULKNER, and THOMAS J. ROGERS

Appeal 2009-002547
Application 10/731,828
Technology Center 3700

Decided: ¹ July 1, 2009

Before DONALD E. ADAMS, RICHARD M. LEOVITZ, and
MELANIE L. McCOLLUM, *Administrative Patent Judges*.

LEOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal from the Patent Examiner's rejection of claims 1, 3-5, 7-10, 12, 13, 15, 18, and 19 as obvious over prior art.

¹ The two-month time period for filing an appeal or commencing a civil action, as provided for in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

Jurisdiction for this appeal is under 35 U.S.C. § 6(b). The obviousness rejections are affirmed.

STATEMENT OF THE CASE

The claims relate to “radioactive seeds” which are radioactive implants used in the treatment of various clinical conditions, such as cancer and restenosis (Spec. 1).

Claims 1, 3-5, 7-10, 12, 13, 15, 18, and 19 are pending and stand rejected by the Patent Examiner as follows:

Claims 1, 3-5, 7-10, 12, 13, 15, 18, and 19 under 35 U.S.C. § 103(a) as obvious over Langton and Bolea (Ans. 3); and

Claim 4 under 35 U.S.C. § 103(a) as obvious over Langton, Bolea, and Kan (Ans. 3).

Claim 1 is representative and reads as follows:

1. A method of sterilising one or more radioactive seeds, which method comprises subjecting the radioactive seeds to dry heat at a temperature of at least 140°C for a minimum of 2 hours to effect sterilisation, and subsequently cooling the radioactive seeds.

OBVIOUSNESS OVER LANGTON AND BOLEA

Claims 1, 3-5, 7-10, 12, 13, 15, 18, and 19 stand rejected under 35 U.S.C. § 103(a) as obvious over Langton and Bolea (Ans. 3).

Statement of the Issue

Claim 1 is directed to a method of sterilizing a radioactive seed by subjecting it to dry heat of at least 140°C for a minimum of two hours. The Examiner found that Langton describes sterilizing a radioactive seed with an

autoclave, which would involve dry heat, but does not explicitly teach a sterilization period of two hours. However, the Examiner contends that the two-hour period would have been obvious to persons of ordinary skill in the art based on Bolea's teachings. Appellants contend that Langton does not teach using dry heat for sterilization purposes and it would not have been obvious to have utilized dry heat of at least 140°C in Langton's process.

The issue in this rejection is therefore whether the Langton and Bolea patents would have been combined by persons of ordinary skill in the art to have achieved a method of sterilizing a radioactive seed by subjecting it to dry heat of at least 140°C for a minimum of two hours.

Principles of Law

"During [patent] examination, the examiner bears the initial burden of establishing a prima facie case of obviousness." *In re Kumar*, 418 F.3d 1361, 1366 (Fed. Cir. 2005). Once prima facie obviousness is established, Appellant has the burden of providing arguments and evidence to rebut it. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

Findings of Fact (FF)

The Langton patent

1. Langton describes a radioactive carrier device comprising radioactive seeds for use in interstitial radiation therapy (col. 1, ll. 5-16).
2. The radioactive seeds are disposed in an elongated, flexible, and bio-absorbable material (col. 2, ll. 38-47).
3. The seeds and bio-absorbable material are placed in a "spacing jig member" with recesses (col. 2, ll. 48-50).

4. “The entire assembly is then heated which causes the elongated material holding the seeds to become semi-rigid” (col. 2, ll. 60-62).
5. “Following the heating process, the bio-absorbable material, upon cooling, will shrink or contract a certain amount” (col. 2, ll. 62-64).
6. The assembly “then is placed within its primary package container” which comprises a polymer package to fit a cavity and a “breathable” cover to allow for sterilization gases to permeate the cover (col. 2, l. 66 to col. 3, l. 5).
7. “The entire assembly within the sealed primary package container then is sterilized by gas (such as ethylene oxide) or gamma irradiation” (col. 3, ll. 7-10).
8. “It is also contemplated that the unit can be both heated/stiffened and sterilized by using an appropriate autoclave cycle, thus producing a ‘one step’ manufacturing process” (col. 3, ll. 10-13).
9. Langton states that the jig member which holds the radioactive seeds “must be able to withstand the temperatures to which the assembly will be subjected to stiffen the bio-absorbable material, e.g., dry heat of 150° C-185° C. or 1 hour, 120° C.-125° C.” (col. 5, l. 66 to col. 6, l. 2).

The Bolea patent

10. Bolea teaches that “[d]ry heat sterilization typically involves exposing the devices being sterilized to temperatures in a range of approximately 180° C, or higher, for at least two hours” (col. 1, ll. 39-42).

Analysis

Claim 1 is drawn to a process of sterilizing radioactive seeds comprising two steps: “subjecting the radioactive seeds to dry heat at a temperature of at least 140°C for a minimum of 2 hours to effect sterilisation” and “cooling the radioactive seeds.” The Examiner found that Langton describes a process of “making and sterilizing” radioactive seeds involving heating and cooling steps as in claim 1 (Ans. 3). The Examiner found that the difference between claim 1 and the Langton reference is that Langton does not describe the sterilization conditions recited in the claim of “at least 140°C for a minimum of 2 hours” (*id.*) However, the Examiner concluded this limitation was obvious in view of Langton’s teaching that the seeds disposed in the container are “stiffened and sterilized at the same time using an autoclave” (*id.*; FF8) and that autoclaves were “known to use steam and dry heat” (Ans. 4). Relying on Bolea, the Examiner found that “[i]t is old and well known in the medical art that when using dry heat for sterilization the typical time period is at least two hours as shown by Bolea column 1 lines 39-42” (*id.*; FF10).

Appellants contend that “Langton does not disclose, teach, or suggest using dry heat for sterilization purposes.” (App. Br. 4). They argue that “Langton clearly only discloses the use of gas or gamma irradiation to sterilize the sheath or an autoclave system to heat/stiffen and sterilize the sheath. (see column 3, lines 5-13).” (*Id.* at 6.) They assert that Langton teaches away from dry heat sterilization because:

If Langton used a dry heat sterilization process it would require strong heating of a sealed capsule containing a volatile radionuclide which would imply an attendant risk of internal

pressure developing. Clearly any rupture of the sheath would cause a serious escape of radioactivity.

(*Id.*)

The Examiner's rejection is supported by a preponderance of the evidence. Langton explicitly discloses that its entire assembly can be "heated/stiffened and sterilized" by autoclave (FF8). While Langton does not teach that the autoclave cycle utilizes dry heat as in the claim, the Examiner found that autoclaves were known to use dry heat (Ans. 4) and that Bolea describes dry heat sterilization conditions that meet the claim limitations (*id.*; FF10). Furthermore, Langton explicitly states that the assembly "will be subjected" to "dry heat of 150° C-185° C." (FF9), dry heat temperatures that fall within the scope of the claim. Appellants have not identified any defect in these finding. Accordingly, as the Examiner has set forth a well-reasoned and fact-based analysis for concluding that claim 1 would have been obvious, the burden of coming forward with rebuttal evidence or arguments shifted to Appellants. *Oetiker*, 977 F.2d at 1445. *See also Hyatt v. Dudas*, 492 F.3d 1365, 1369-70 (Fed. Cir. 2007).

Appellants contend that dry heat sterilization would not have been chosen by the skilled worker because of the risk of rupture by the pressure produced by the sterilization process. (App. Br. 5 & 6 (as quoted above)).

Arguments provided by counsel cannot take the place of evidence lacking in the record. *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 595 (Fed. Cir. 1997). As pointed out by the Examiner, Appellants have "presented no evidence that there is any danger of rupture" to Langton's device (Ans. 9). To the contrary, Langton's "breathable" cover which allows sterilization gases to "permeate" it (FF6) would reasonably be understood to allow gases (i.e., air when dry heat is used) to flow out from

the assembly, as well. Thus, while we have considered their argument, we conclude that the evidence of record – Langton’s autoclave teaching (FF8) and statement that dry heat may be used in its process (FF9) – weighs heavily against it. In sum, Appellants have not produced sufficient evidence of the unobviousness of choosing dry heat sterilization, rather than gamma or gas sterilization as disclosed in the Langton patent (FF7).

OBVIOUSNESS OVER LANGTON, BOLEA, & KAN

Claim 4 stands rejected under 35 U.S.C. § 103(a) as obvious over Langton, Bolea, and Kan (Ans. 3).

Claim 4 is directed to the method of claim 1, where “the radioactive seeds are loose.” The Examiner found that Kan “teaches sterilizing loose seeds with steam” (Ans. 5). The Examiner concluded that it would have been obvious to one of ordinary skill in the art at the time “to use dry heat sterilization with the device of Kan as a substitution of functionally equivalent elements as taught by” Langton and Bolea (*id.* at 6). As Appellants do not identify any deficiency in the rejection, and we find none, we affirm the rejection for the reasons stated by the Examiner.

CONCLUSION OF LAW

A person of ordinary skill in the art would have combined the Langton and Bolea patents to have achieved the method of claim 1 comprising sterilizing a radioactive seed by subjecting it to dry heat of at least 140°C for a minimum of two hours.

SUMMARY

We affirm the obviousness rejection of claim 1. Claims 3-5, 7-10, 12, 13, 15, 18, and 19 fall with claim 1 because separate arguments for their patentability were not provided. *See* 37 C.F.R. § 41.37(c)(1)(vii).

We affirm the obviousness rejection of claim 4.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

dm

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